



Disclosure to Promote the Right To Information

Whereas the Parliament of India has set out to provide a practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, and whereas the attached publication of the Bureau of Indian Standards is of particular interest to the public, particularly disadvantaged communities and those engaged in the pursuit of education and knowledge, the attached public safety standard is made available to promote the timely dissemination of this information in an accurate manner to the public.

“जानने का अधिकार, जीने का अधिकार”

Mazdoor Kisan Shakti Sangathan

“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

Jawaharlal Nehru

“Step Out From the Old to the New”

IS 6812 (2003): Knee Joint, Uniaxial for Below Knee Prosthesis [MHD 10: Medical Laboratory Instruments]

“ज्ञान से एक नये भारत का निर्माण”

Satyanaaranay Gangaram Pitroda

“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartṛhari—Nītiśatakam

“Knowledge is such a treasure which cannot be stolen”



BLANK PAGE



PROTECTED BY COPYRIGHT

भारतीय मानक
घुटने के जोड़ों, घुटनों से नीचे के कृत्रिम अंग
रोपण के लिए एकाक्ष की विशिष्टि
(दूसरा पुनरीक्षण)

Indian Standard
KNEE JOINT, UNIAXIAL FOR BELOW KNEE
PROSTHESES — SPECIFICATION
(*Second Revision*)

ICS 11.040.40, 11.180.10

© BIS 2003

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Artificial Limbs, Rehabilitation Appliances and Equipment for the Disabled Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1972. In the first revision more emphasis was given on functional and performance requirements. This revision has been taken up to incorporate certain modifications so as to bring it in line with the modern manufacturing practices. Accordingly in the present revision 2 types of construction of knee joint have been covered and material requirements specified.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final values, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value shall be the same as that of the specified value in this standard.

Indian Standard

KNEE JOINT, UNIAXIAL FOR BELOW KNEE PROSTHESES — SPECIFICATION

(Second Revision)

1 SCOPE

1.1 This standard specifies the general requirements for the uniaxial knee joint, for below knee prostheses.

2 REFERENCES

2.1 The following standards contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No.	Title
1570 (Part 5) : 1985	Schedules for wrought steels: Part 5 Stainless and heat-resisting steels (<i>second revision</i>)
2004 : 1991	Carbon steel forgings for general engineering purposes (<i>third revision</i>)
4398 : 1994	Carbon-chromium steel for the manufacture of balls, rollers and bearing races (<i>second revision</i>)

3 TYPES

3.1 The knee joint shall be of the following types:

- a) *Forged Type Construction* — As shown in Fig. 1.
- b) *Precision Casting Type Construction* — As shown in Fig. 2.

4 SHAPE AND DIMENSIONS

4.1 The shape and dimensions of the knee joint shall be as given in Fig. 1 and Fig. 2.

4.2 Inner (medial) joint is the mirror image of the outer (lateral) joint. Two such joints form one set.

5 MATERIAL

5.1 Forged steel shall conform to IS 2004.

5.2 Ball race screw and bearing balls shall conform to IS 4398.

5.3 The joint knee, tower shall be made of stainless steel of Designation 12Cr13, 13Cr13 or 04Cr19Ni9 of IS 1570 (Part 5).

6 FUNCTIONAL REQUIREMENTS

6.1 There shall not be any frictional, jerky or mediolateral moments at the joint.

6.2 Male and female components shall form an angle of 60° or less when closed, and 175° when opened.

7 CONSTRUCTIONAL REQUIREMENTS

7.1 The joint shall have ball race screw and bearing balls with arrangements to replace other ball race screw or balls or both.

7.2 Spider locking washer shall be used to prevent accidental unscrewing.

8 WORKMANSHIP AND FINISH

8.1 All components shall have good finish and be free from mechanical flaws.

8.2 The components, lower and upper, shall be forged/investment cast.

8.3 The forged/investment castings shall be supplied in annealed condition.

8.4 Stainless steel components shall be butted and shall have mall finish.

9 CYCLIC TEST

9.1 The complete assembled unit shall be tested for 20 000 cycles in a suitable testing fixture to simulate the actual conditions. After completion of the test the functioning of the joint shall remain unimpaired.

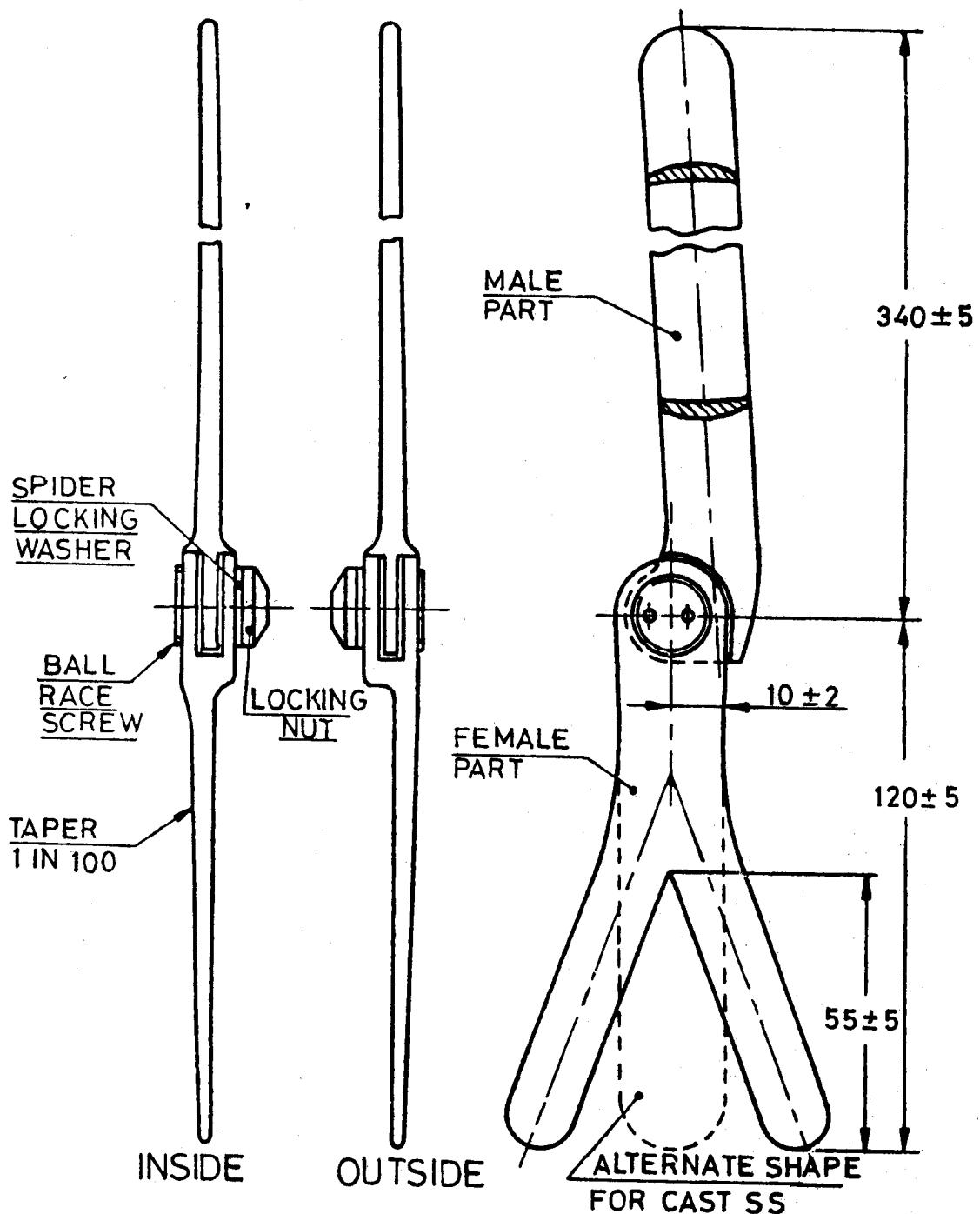
10 MARKING

10.1 The joint shall be clearly marked with the manufacturer's name, initials or recognized trade-mark.

10.2 BIS Certification Marking

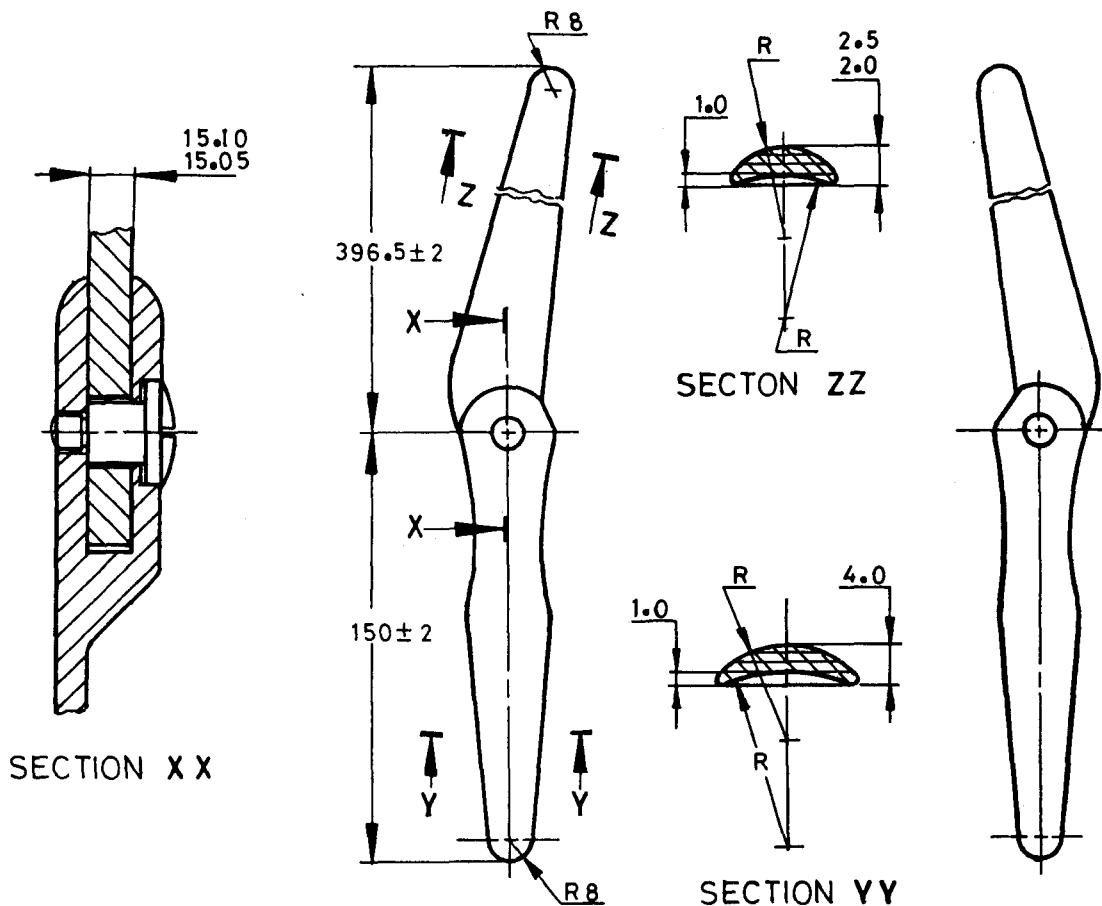
The knee joint may also be marked with the Standard Mark.

10.2.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards*



All dimensions in millimetres.

FIG. 1 KNEE JOINT UNIAXIAL ASSEMBLY, TYPICAL



All dimensions in millimetres.

FIG. 2 JOINT KNEE FREE

Act, 1986 and the Rules and Regulations made there under. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers, may be obtained from the Bureau of Indian Standards.

11 PACKING

11.1 Packing shall be as agreed to between the purchaser and the manufacturer, however it is recommended that the joint may be packed in the form of a kit.

12 SAMPLING

12.1 A sampling scheme and criteria for acceptance shall be as agreed to between the purchaser and the manufacturer. However a recommended scheme is given in 12.2 to 12.4.

12.2 Lot

All the sets of knee joints of the same type shall be grouped together to constitute a lot. Each lot shall be tested for the requirements of this specification.

12.3 Each set of knee joints, uniaxial for below knee conventional prostheses shall be examined for shape and dimensions (4), functional requirements (6), constructional requirements (7), workmanship and finish (8). All those sets which fail in one or more of the above requirements shall be rejected and only the satisfactory sets of joints shall be accepted.

12.4 For the purpose of cyclic test, one assembled unit shall be randomly selected and be subjected to appropriate test. The sample unit shall pass if the lot is to be accepted under this clause.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act, 1986* to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in the course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Director (Publications), BIS.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards : Monthly Additions'.

This Indian Standard has been developed from Doc : No. MHD 10 (2735).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110 002
Telephones : 2323 0131, 2323 3375, 2323 9402

**Telegrams: Manaksantha
(Common to all offices)**

Regional Offices:

Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg
NEW DELHI 110002

Telephone

{ 2323 7617
2323 3841

**Eastern : 1/14 C. I. T. Scheme VII M, V. I. P. Road, Kankurgachi
KOLKATA 700 054**

$$\left\{ \begin{array}{l} 23378499, 23378561 \\ 23378626, 23379120 \end{array} \right.$$

Northern : SCO 335-336, Sector 34-A, CHANDIGARH 160 022

603843
609285

Southern : C. I. T. Campus, IV Cross Road, CHENNAI 600 113

$$\left\{ \begin{array}{l} 2254\,1216, 2254\,1442 \\ 2254\,2519, 2254\,2315 \end{array} \right.$$

Western : Manakalaya, E9 MIDC, Marol, Andheri (East)
MUMBAI 400 093

{ 28329295, 28327858
28327891, 28327892

Branches : AHMEDABAD. BANGALORE. BHOPAL. BHUBANESHWAR. COIMBATORE. FARIDABAD. GHAZIABAD. GUWAHATI. HYDERABAD. JAIPUR. KANPUR. LUCKNOW. NAGPUR. NALAGARH. PATNA. PUNE. RAJKOT. THIRUVANANTHAPURAM. VISAKHAPATNAM.